



USAID
FROM THE AMERICAN PEOPLE

LOGISTICS FACT SHEET FOR QUALITY CONTROL OF DRUGS GPHF-MINILAB[®]



BRAND AND MANUFACTURER

Sales Information

German Pharma Health Fund e.V.
(GPHF)
Postfach 15 23, 61405 Oberursel nr.
Frankfurt, Germany
Tel.: +49-6171-50399-0
Fax: +49-6171-50399-20
Email: info@gphf.org
Website: www.gphf.org

Supplier

Technologie Transfer Marburg e.V.
(TTM)
Auf der Kupferschmiede 1, 35091
Coelbe, Germany
Tel.: +49-6421-87373-0
Fax: +49-6421-87373-7
Email: ttm@ttm-germany.de

For technical questions about
equipment and testing procedures and
references from current users:

Dr. Richard W. O. Jähnke
German Pharma Health Fund e.V.
(GPHF)
Postfach 15 23, 61405 Oberursel nr.
Frankfurt, Germany
Tel.: +49-6171-50399-0
Fax: +49-6171-50399-20
Email: info@gphf.org

KIT INFORMATION

Counterfeiting of pharmaceuticals and the proliferation of substandard drugs constitute a serious health risk, especially in the developing world where drug quality control systems are not always readily available. Experts assume that currently as much as 7 percent of the world's total pharmaceutical sales is counterfeited or of substandard quality.

The GPHF-Minilab[®]* is a mini-laboratory used in developing countries by medical store and hospital managers, drug inspectors, and other authorities to detect counterfeit and substandard pharmaceuticals and to provide basic quality control of drugs.

* Developed by the German Pharma Health Fund (GPHF), a nonprofit organization that promotes pilot projects for the improvement of health services in developing countries.

DRUGS AND CATEGORIES

Analgesics (pain relievers)

Acetylsalicylic Acid, Metamizole,
Paracetamol

Antiasthmatics

Aminophylline, Salbutamol

Antibiotics

Amoxicillin, Ampicillin, Cefalexin, Chloramphenicol, Ciprofloxacin, Cloxacillin, Cotrimoxazole, Erythromycin, Metronidazole, Phenoxymethylpenicillin, Tetracycline

Antidiabetic

Glibenclamide

Antifungal

Griseofulvin

Anthelmintic

Mebendazole

Antimalarials

Amodiaquine, Artemether, Artesunate, Lumefantrine, Chloroquine, Mefloquine, Primaquine, Quinine, Sulfadoxine/Pyrimethamine

Antiretrovirals (ARVs)*

Didanosine, Indinavir, Lamivudine, Nevirapine, Stavudine, Zidovudine

* On special request only and at additional cost

Antituberculosis

Ethambutol, Isoniazid, Pyrazinamide, Rifampicin

Diuretic

Furosemide

Steroid

Prednisolone



May 2006

This publication was produced for review by the United States Agency for International Development. It was prepared by the DELIVER project.



DELIVER
No Product? No Program. Logistics for Health

CURRENTLY USED IN

Latin America & the Carribean

- Bolivia
- Colombia
- Grenada
- St. Lucia
- Venezuela
- Brazil
- Ecuador
- Guyana
- Surinam

Africa

- Cameroon
- Eritrea
- Ghana
- Kenya
- Mali
- Niger
- Senegal
- Sudan
- Togo
- Congo
- Gabon
- Guinea
- Liberia
- Mozambique
- Nigeria
- Sierra Leone
- Tanzania
- Zimbabwe

Asia

- Afghanistan
- Cambodia
- Georgia
- Indonesia
- Nepal
- Pakistan
- Sri Lanka
- Vietnam
- Bangladesh
- China
- India
- Myanmar
- Laos
- Philippines
- Thailand

Middle East

- Palestine

TESTING PROCEDURES

Visual Inspection Test

A comparison of solid dosage forms, including the packaging material, in order to rapidly reject crudely presented formulations. The test includes a search for deficiencies in the labeling, packaging, and dosage forms in comparison with the descriptions given in the GPHF-Minilab® manual included in the start-up package.

Disintegration Test

This test requires that all instantly soluble tablets and capsules disintegrate in water at a certain temperature within a designated timeframe, as specified in the main manual. This is a simple test for preliminary assessments of deficiencies related to drug solubility and availability. All instantly soluble tablets and capsules must pass the Disintegration Test. The manual included in the GPHF-Minilab® start-up package provides a detailed description of this test.

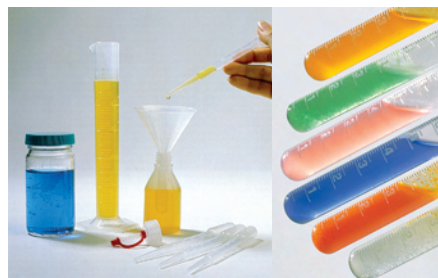
Color Reaction Test

A simplified test for a quick color check of any drug present against a standard in order to verify the drug's identity. A sample of the drug is crushed and mixed with the appropriate reagents to create a color reaction. The color is verified using the reference standards given in the GPHF-Minilab® manual on color reactions. If the drug fails this step, it is recommended to reject the drug and conserve resources by not conducting the TLC testing below.

Thin Layer Chromatography (TLC) Test

A semi-quantitative test against a standard to check the amount of active ingredient present to verify a drug's potency. This test requires one whole unit of an oral solid dosage to be dissolved in a known volume of extraction solution. The sample solution is applied to a thin layer chromatoplate (supplied in the GPHF-Minilab® start-up package), allowed to develop for 15 minutes in a solvent, dried using a hot plate, analysed using an ultra-violet (UV) lamp, and finally stained with iodine to detect any spots failing to appear in the UV detection. Detailed instructions for the analysis of each drug are given in the GPHF-Mini-

lab® main manual on TLC.



SUPPLY CHAIN IMPLICATIONS

| | Color Reaction Kit | TLC Kit |
|---|---|--|
| Equipment Included in Kit | rulers, thermometer, timer, labeling tape and pen, hot plate, sample preparation equipment (test tubes, test tube rack, mixing beakers, scalpel/blade, spatula, filter paper, tweezers, scissors, pestle, funnel, pipettes, pipette rack)* universal pH indicator testing paper, dropping bottle and sealer cap, glass stirring rod, measuring cylinders, glass bottles with closures, transfer pipettes, micro-spoon, adapter plug, alcohol lamp, methylated spirit (alcohol) - 1 L, safety spectacle, test-tube brush | aluminum foil, glass bottles with closures, pumpette, pencil, pencil sharpener, Merck TLC aluminum plates, TLC developing chamber, iodine staining chamber, battery-powered UV lamps of various preset wavelengths with replacement batteries, authentic secondary reference standards (ARV secondary reference standards supplied on request) |
| Reagents and Solvents Included in Start-up Package | acetone (1 L); glacial acetate acid (1 L); methanol (1 L); ninhydrin (10 g); sulfuric acid 96% (1 L)* copper (II) acetate, monohydrate (100 g) 4-(dimethylamino)-benzaldehyde (25 g) fast red TR salt (10 g) ferric (II) chloride tetrahydrate (50 g) ferric (III) chloride solution 10% (0.25 L) formaldehyde 37% (50 mL) hydrochloric acid solution 36% (1 L) hydrogen peroxide solution 30% (1 L) phenol crystals (or liquid phenol) (100 g) potassium dichromate (50 g) sodium hydroxide pellets (500 g) | ammonia solution 25-26% (50 mL) disodium or tripotassium edetate (50 g) ethylacetate (1 L) glacial acetic acid (1 L) hydrochloric acid solution 32-36% (1 L) iodine (50 g) magnesium chloride hexahydrate (100 g) methanol (1 L) ninhydrin (10 g) toluene (1 L) |
| | Capacity sufficient for 3,000 color reaction runs | Capacity sufficient for 1,000 TLC runs |
| Packaging and Shipping Information | 1 protective case (black with pre-formed dividers/pockets) 62 x 50 x 22 cm 14 kg | 1 protective case (black with pre-formed dividers/pockets, wheels and extension handle) 83 x 52 x 29 cm 23 kg |
| | Start-up package: reagents and solvents 20–22 boxes (approx. 50 kg) | |
| | Approximately 90 kg as ready-packed palette for worldwide delivery by air (40 kg for suitcases and 50 kg for reagents) | |
| | Order will be shipped within 3 weeks from when order is received and the invoice is settled. | |
| Shelf Life | 5 years for reagents and solvents in their original packaging. | <ul style="list-style-type: none"> • 2 years for authentic secondary reference standards. • Less than 2 years for authentic secondary reference standards for ARVs. |
| Storage Conditions | <ul style="list-style-type: none"> • Store at room temperature, avoiding direct sunlight. • No special storage required for the quantities of chemicals supplied. | |
| Installation and Use | <ul style="list-style-type: none"> • Can be used outdoors and indoors. • Can be mounted on a bench top or office table. • Fits all electrical sockets and voltages. • Sufficient air ventilation needed, e.g., fan and open window, when using indoors. • Requires access to running water for cleaning equipment. | |

* Included in both the Color Reaction Kit and the TLC Kit.

ESTIMATED PRICE

Minilab Start-up Package¹

- 3,100 €
- U.S.\$3,760 without optional features

Transport to Country²

- 800 ± 100 €
- U.S.\$970 ± U.S.\$120

Transport in Country

- 120 €
- U.S.\$145

Duties

- 1000 €
- U.S.\$1,213

Total

- 4,750 € (about 5 €/assay)
- U.S.\$5,760 about U.S.\$6/assay

One Week Training

- 450 €/person
- U.S.\$546/person

Travel Expenses³

- 2,500 €
- U.S.\$3,032

Resupply of Reagents & Solvents⁴

- Minimum order: 10 €
- U.S.\$12

OPTIONAL FEATURES

(with minimal increase in weight and volume)

- Authentic secondary reference standards for ARVs. Cost: approximately 7 € (U.S.\$8.50) for each ARV secondary reference standard.

Note: As of May 2004, there is a donated stock of these materials, so this cost is only for additional packaging and handling fees for each tube (containing 20 samples of authentic reference tablets/capsules). Cost for stock falling below a shelf life of 6 months is negotiable. If this donated stock is not available, the actual market value of the ARV drug will be applicable.

- Small battery-driven pocket balance with a precision of 0.01 g for testing the quality of bulk drug substances, uniformity of tablet and capsule mass, and easy preparation of test solutions. Cost: 160 € (U.S.\$194).

LIMITATIONS

- Reagents are supplied separately and need an adequate amount of storage space, although there are no special storage requirements for the chemicals.

TRAINING

Training on the Minilab's operational procedures is offered locally, or in Germany by the:

- Medical Mission Institute Würzburg, mi-appro@mailuni-wuerzburg.de
- German Medical Aid Organization medeor;info@medeor.org
- GPHF-Minilab® Project Manager, info@gphf.org.

¹ Price valid until Dec. 31, 2005.

² U.S.\$ value as of June 23, 2005.

³ Price of transport and duties varies by destination.

⁴ Price lists are available from the supplier.

The author's views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

DELIVER

John Snow, Inc.

1616 N. Ft. Myer Drive

11th floor

Arlington, VA 22209

USA tel: 703-528-7474 fax 703-528-7480

deliver@jsi.com